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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,986	03/16/2004	Leonard D. Kohn	103287.0522855	3062

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

NOTIFICATION DATE	DELIVERY MODE
02/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/801,986	KOHN ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-64 and 69-107* is/are pending in the application.

4a) Of the above claim(s) *55-57 and 69-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54 and 58-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment and Response filed November 19, 2007 is acknowledged. Claims 65-68 are canceled. Claims 54-64 and 69-107 are pending.

On May 15, 2007 Applicants elected Group I, drawn to methods for inhibiting cell adhesion, optionally wherein the cell adhesion is VCAM-1 mediated, claims 54, 55, 57-95 and 97. Applicants further elected the specie 1-methyl-5-phenyl-imidazoline-2(3)-**thione**, also known as 5-phenylmethimazole.

Claims 55-57 and 69-107, are presently withdrawn from consideration by the Examiner, as drawn to non-elected subject matter, 37 CFR 1.142(b). Claims 54 and 58-64, drawn to methods for inhibiting cell adhesion, wherein the method is used to treat a cardiovascular disease, comprising administering 5-phenylmethimazole, represent the subject matter now under consideration.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The rejections set forth below constitute the only rejections currently applied to the instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54 and 58-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 67 of copending Application No. 10/912948. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the co-pending application is drawn to the administration of methimazole derivatives and/or cyclic thione derivatives, which encompass 5-.phenyl methimazole, for use in the treatment of diseases, disorders, conditions or symptoms mediated by cytokines.

Claims 54 and 58-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 139-304 of copending Application No. 11/130922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application are drawn to the administration of methimazole derivatives and/or cyclic thione derivatives, which encompass 5-phenyl methimazole, for use in the treatment of various autoimmune/inflammatory diseases that encompass those presently claimed.

Claims 54 and 58-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 61-64 of copending Application No. 10/830898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application are drawn to the administration of methimazole derivatives and/or cyclic thione derivatives, which encompass

5-phenyl methimazole, for use in the treatment of various autoimmune diseases, disorders, conditions or symptoms that encompass those presently claimed.

These are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 54 and 58-64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-33 and 42-44 of U.S. Patent No. 6,365,616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to administration of methimazole derivatives and/or cyclic thione derivatives, which clearly encompass 5-phenyl methimazole, for use in the treatment of autoimmune diseases, as for example, Graves' disease.

Applicants have chosen to hold these issues in abeyance.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54 and 58-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohn et al., U.S. Patent 6,365,616.

Kohn teaches the administration of 5-methyl methimazole to treat autoimmune diseases such as systemic lupus erythromatosus, characterized by a potentially cardiovascular disorder. See column 13 where a particularly preferred subset of methimazole derivatives is described at line 30 where X = S, Y, R^2 in the 3-position, R^1 and R^4 = H and R^2 in the 1-position is methyl. Further, see Table 15, column 49, where 5-phenylmethimazole is, *inter alia*, specifically

disclosed. According to The Merck Manual, which is presented for evidentiary purposes only, noninfective endocarditis is a cardiovascular disease that occurs in a certain population of patients having systemic lupus erythromatosus.

The inhibition or suppression of cell adhesion, optionally VCAM-1 and/or E-selectin mediated, or IRF-1 dependent VCAM-1 mediated cell adhesion, as well as cytokine-induced cell adhesion, optionally wherein the cytokine is TNF-alpha, are inherent mechanisms of action following the administration of 5-phenyl methimazole.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

There is no requirement that a person of ordinary skill in the art would have recognized the inherent features at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm., Inc., 339 F. 3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2004) ("[T] he fact that a characteristic is a necessary feature or result of a prior art embodiment (that is sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 30, 2008

Phyllis G. Spivack

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PHYLLIS SPIVACK
PRIMARY EXAMINER